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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,051	12/13/2000	Hua Zhu Ke	PC9344BRTR	6748

23416 7590 07/07/2004

CONNOLLY BOVE LODGE & HUTZ, LLP  
P O BOX 2207  
WILMINGTON, DE 19899

EXAMINER
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LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/736,051

**Applicant(s)**

KE ET AL.

**Examiner**

Louise N. Leary

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4-8-2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69 and 72 is/are allowed.
- 6) ☒ Claim(s) 73-75, 79, 80, 84-89 and 92-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4-8-2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-14,16-30,33-42,45-50,52-55,57-62,65-69,72-75,79,80,84-89 and 92-108.

1. Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89 and 92-108 are pending in this application.

Claims 5, 15, 31-32, 43-44, 51, 56, 63-64, 70-71, 76-78, 81-83 and 90-91 have been canceled per applicant's request.

2. The rejection of claims 93, 97, 101-102, and 106 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Lax et al (Endocrinology, V. 113(5), p 1043-1055, (1983) has been withdrawn in view of applicant's arguments presented April 8, 2004.

3. The rejection of claims 93, 95, 97, 99, 101-102, 104 and 106 under 35 USC 103(a) as being unpatentable over Gertz et al (WO 95/11029, April 1995) in combination with Wronski et al (Endocrinology, V. 132(2), pp. 823-831, (1993) and Evans et al (Endocrinology, V. 134(5), p 2283-2238, (1994) (Abstract Only) has been withdrawn in view of applicant's arguments presented April 8, 2004.

4. The objection to claims 94, 96, 98, 100, 103, 105 and 107-108 as being dependent upon a rejected base claim has been withdrawn.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-75, 79-80, 84-89 and 92-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino et al (US 6,110,932 patented August 29, 2000).

Carpino et al disclose a pharmaceutical composition comprising selecting raloxifene, tamoxifen or idoxifene in combination with a parathyroid hormone or growth hormone. With respect to the "pharmaceutical carrier" described in the instant claims, Carpino et al disclose a pharmaceutical composition comprising the compounds of Formula I in association with a pharmaceutical carrier. See the abstract; column 20, lines 46-50; and column 25, lines 30-46. Also, Carpino et al disclose "a method for the treatment of osteoporosis which comprises administering to a human or other animal with osteoporosis a combination of an

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estrogen agonist or antagonist such as tamoxifen, droloxifene, raloxifene and idoxifene and a compound of Formula I...". See column 20, lines 46-59 and column 26, lines 1-68. Regarding instant claim 84 which recites "the condition which presents with low bone mass is osteoporosis", Carpino et al disclose a treatment method that uses the composition describe above for treating osteoporosis in a human or other animal in need of this treatment. Further, regarding the "low bone mass" instant limitations, Carpino et al also describe treating humans and animals in need of stimulating osteoblasts, bone remodeling, cartilage growth, inhibiting bone resorption, preventing osteoporosis, stimulating bone formation and increasing bone mineral density. See the abstract; column 20, lines 46-59; column 25, lines 30-46; column 26, lines 1-68; and column 27, lines 1-68.

In regards to the instant methods for administering the active compounds and the time periods recited for administration, Carpino et al disclose administering two active compounds in a pharmaceutical combination which addresses substantially simultaneous administration. Note the abstract. With respect to administering one active compound before administering another active compound, it is noted that Carpino et al disclose administering one active compound and optionally adding another active compound before administering to a patient in need. Further, it is noted that Carpino et al disclose administering the active compounds claimed in the instant invention to a human or animal in need of treatment for osteoporosis or related conditions. Note the abstract and column 31, lines 1-53.

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With respect to instant claim 93, Carpino et al disclose a combination comprising a growth hormone secretagogue compound and estrogen agonist/antagonist. Note the abstract and column 20, lines 46-59. Also, Carpino et al disclose the growth secretagogue 2-amino-N-[2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl]-isobutyramide and the L-tartaric acid salt in combination with an estrogen agonist/antagonist to treat osteoporosis. See the abstract; column 8, lines 54-68 and column 20, lines 46-59. In addition, Carpino et al disclose (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol used in combination with a Formula I compound to treat osteoporosis. See the abstract and column 20, lines 46-59. Further, Carpino et al disclose a pharmaceutical composition comprising the compounds of Formula I in association with a pharmaceutical carrier and an estrogen agonist/antagonist to treat osteoporosis. Note the abstract; column 20, lines 46-59 and column 30, lines 58-64.

Thus, Carpino et al disclose or suggest the invention claimed except for describing a kit.

However, with respect to the instant kit, it is noted that Carpino et al disclosed each of the relevant chemical components in the kit and describe methods for using the components for the same functions set forth in the claims. Carpino et al disclose or suggest all the instant claim limitations except for describing a kit comprising the relevant chemical compounds recited which was deemed to be an obvious modification of the Carpino et al invention at the time

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this invention was made because Carpino et al disclose or suggest each of the relevant chemical components in the kit and describe methods for using the components for the same functions set forth in the claims. Hence, the Carpino et al anticipates or renders obvious the claimed invention.

The burden of proof is on applicants to show patentably distinct differences between the Carpino et al disclosure and the present invention as claimed.

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6. Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, and 72 are allowable over the prior art of record.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 9:30 to 6:30pm.

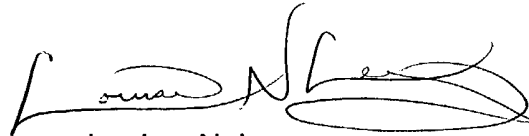
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through



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Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Louise N. Leary", with a large, stylized flourish at the end.

Louise N. Leary  
Primary Examiner  
Art Unit 1654  
July 1, 2004

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